
CON Task Force Issue Brief

Certificate of Need Review Process

- Completeness Review
- Redocketing Rules

Statement of the Issue

How can the Certificate of Need review process be strengthened?

Summary of Public Comments

Adventist HealthCare comments that certain timelines in the CON review process are unrealistic. One example is the quick turnaround often required for completeness questions both on the part of MHCC and the applicant. This may result in inaccurate or incomplete information provided, and may ultimately slow the overall review process or render it less effective. Adventist HealthCare also recommended that hospitals not be required to re-docket an application for changes to the project beyond the applicant's control.

Andrew L. Solberg recommended that completeness questions only address whether a component of the application was not completed. According to Solberg, completeness review should not be a judgment on how well it was completed. Solberg states that this should be reserved for additional information questions following docketing of the application. In addition, Solberg states that in the past a Reviewer could request that an applicant make changes to a proposed project at any time during the review. This flexibility was deleted from the regulations approximately five years ago. According to Solberg, the CON regulations should state that changes to a project under review resulting from requests made by Commission Staff or a Commission Reviewer may be made at any time and will not result in re-docketing of the application.

CareFirst believes that it would be appropriate for interested parties to have the opportunity to submit completeness questions for the staff's consideration during staff's review of applications for completeness. According to CareFirst, some CON applications are docketed as complete, even though applications have not provided some mandated information.

Carroll Hospital Center recommended that the completeness review process be streamlined by limiting it to one set of questions and to matters of technical completeness. A second set of questions should only be allowed if the first completeness responses are incomplete. While Carroll Hospital Center understands that additional or clarifying information may be necessary in order for staff to complete its review and understand the project, this information can be obtained after docketing and during the review process.

Comments from **Civista Medical Center** state that the process of completeness review should take no more than one week and should only be undertaken to assure that the applicant has completed all of the necessary items in the application form set. According to Civista, the practice of extending the completeness review period to conduct a substantive analysis of a submitted CON application and having multiple rounds of completeness review questions and responses is simply wrong. According to Civista, this practice is done because there is a loophole in the law which requires that the MHCC will act on a CON application within 90/150 days and the MHCC has interpreted that to mean to act on a "complete" CON application that is docketed for review. According to Civista, MHCC has given itself no time limits by simply refusing to docket what are otherwise "complete" CON applications.

James A. Forsyth, Esq. stated that the Commission should eliminate delays in completeness review by adhering to the traditional requirement that it is a quantitative rather than qualitative review. In cases where Staff desires more information or has questions, Staff should adhere to regulatory provisions which give them the authority to request additional information. This would avoid delays in docketing applications which result in lengthier reviews and the attendant expense.

Howard Sollins, Esq., on behalf of the **Health Facilities Association of Maryland**, states that the distinction between completeness questions and "additional information" questions should be maintained. When an application has addressed all the criteria, it should be docketed as complete, even if there are additional questions to be answered. According to Sollins, while there is a deadline for nearly every phase in the CON process, there is no deadline within which the MHCC staff replies to responses to completeness questions.

LifeBridge Health recommended that completeness questions and requests for additional information be limited to matters needed to assess compliance with applicable standards. According to LifeBridge, an inordinate amount of time is spent responding to questions that seem to have no bearing on the approvability of an application.

The Maryland Hospital Association (MHA) stated that Commission staff currently makes little or no distinction between questions related to "completeness" and those having to do with "additional information". According to MHA, the Commission for a number of years has gone well beyond the spirit of the regulations and asked for substantive additional information as part of its completeness review. MHA believes that this lengthens the review process inappropriately. Completeness questions should only address whether a particular component of the application was not completed. Completeness review should not include an evaluation of the applicant's response to these components of the application. MHA states that docketing should occur once completeness is established and should not be held up for requests for additional information. MHA urges that the original spirit of the completeness review be restored so that it addresses only whether the necessary application components are complete. MHA recommended that all questions from Commission staff or Reviewers be asked within 45 days of docketing and be focused on matters that are both relevant and important to whether CON approval may be granted.

MHA also recommended that the regulations be modified to eliminate the need for re-docketing due to: requests made by Commission staff or Commission Reviewers; changes made to the SHP during the application process; or, changes made in regulation to bed need during the application process.

Barry Rosen, Esq. states that applications have become more tedious and more costly for applicants. According to Rosen, some completeness questions appear to be asked because the questioners are curious, not because the answers bear a direct relationship to the underlying reasons for the Certificates of Need. Applications and follow-up questions should be streamlined.

The **Southern Maryland Hospital Center** (SMHC) commented that completeness reviews should be restricted to whether necessary application components are technically complete. In addition, the Hospital recommended that the Commission be judicious about asking additional questions. SMHC also recommended the elimination of unnecessary re-docketing.

Background

The current procedural regulations that govern the CON process (COMAR 10.24.01.08C Completeness Review and Docketing) provide that:

- (1) Staff has 10 days in which to conduct a “completeness” review;
- (2) Applicants have 10 days in which to respond to staff’s questions generated during the completeness review;
- (3) Completed applications are to be docketed – applications lacking necessary information can be dismissed and returned;
- (4) 10 day extensions to supply required information can be approved by staff (only with consent of all applicants in comparative reviews);
- (5) Staff may request additional supplementary information at any time after docketing.

Applicants frequently make changes to certificate of need applications after docketing, sometimes triggering a “re-docketing” of the application pursuant to COMAR 10.24.01.08E.

Only “modifications” require re-docketing – changes that do not involve certificate of need regulated facilities or services do not constitute “modifications” requiring re-docketing. Applicants may:

- (1) Modify applications at any time up until 45 days after docketing;
- (2) In comparative reviews, modify an application only with consent of all the applicants after the 45th day; and
- (3) In non-comparative reviews, (a) reduce costs, (b) reduce annual projected revenue, (c) reduce beds and services or (d) make changes to respond to the changes in the State Health Plan at any time (only with consent of other applicants in comparative reviews).

Re-docketing permits public notice of and response to the changed application. Consequently re-docketing also extends the Commission’s time to approve or deny an application.

Issues and Options

The Task Force received a number of comments regarding various components of the CON review process, including completeness review, requests for additional information, and re-docketing rules. Comments received regarding completeness review fall into four general categories, including what specific information is required for the Commission to find an application complete in order to initiate the review, the length of time that should be permitted for the Commission to conduct completeness review, the length of time that applicants should be permitted to respond to completeness review, and the role of interested parties in completeness review. Comments were also received concerning the delay caused by the requirement for re-docketing for an applicant that makes certain changes to

an application. Taken together these comments raise issues about the structure and timeliness of the project review process.

One option is to maintain the current framework for review which involves a completeness review process designed to obtain information necessary to make a decision on the application. In practice, this can involve more than one round of completeness questions and reliance on written communication between Commission staff and the applicant. Following docketing of the application, a Reviewer's Recommended Decision or staff recommendation is issued for consideration by the Commission. Under current rules, there is limited ability to hold meetings with applicants in reviews that involve interested parties. As a result, the Reviewer and staff are restricted in their ability to assist in resolving problems with an application.

Another option is to restructure the review process approach as follows:

- Require two conferences as a standard feature of the review of any CON application; and
- Make related legal/regulatory changes that allow for changes in a project that bring it in closer conformance with the staff or Reviewer's analysis, without penalizing such change by adding more process or time to the review.

The first conference is an Application Review Conference ("ARC") between staff and the applicant, which can be face-to-face or by phone conference, scheduled within the approximate time frame at which the staff currently issue completeness questions. The second is a Project Status Conference ("PSC") between any appointed Reviewer, the staff, the applicant, and any interested parties, in person or by phone.

Application Review Conference

- The format of this conference should be a walk-through of the application and its appendices at which the staff will provide the applicant with its views on the completeness of each question or information requirement outlined in the application;
- The conference will serve to formulate the written completeness review questions with input from both staff and the applicant; and
- Because of the conference, the completeness questions, prepared by staff and given to the applicant within a reasonably short period after the ARC, will be fewer and limited to more substantive issues which could not be fully addressed at the conference or which require development of information or analyses by the applicant; and better understood by the applicant because of the applicant's participation in framing the questions at the ARC.

Project Status Conference

- A Project Status Conference will be held to address those standards and review criteria which present a problem for approval of the project. Prior to this meeting, the Reviewer or staff will send a memorandum to the applicant and interested parties outlining the areas of concern so that the applicant can have appropriate persons attend the PSC.
- The PSC will be structured to allow the applicant and interested parties to ask questions about the status of the project and provide comment regarding the identified issues;
- A written summary of the PSC will be prepared for the record, along with a statement of applicant revisions to the Summary, if desired by the applicant;
- Following the PSC, the applicant will have an appropriate period of time to make changes, if desired, to the project, which cure the problems or deficiencies identified at the

PSC, without the requirement for re-docketing. Each interested party will have a 10 day period in which to file comments on changes to the project.

This option is intended to allow for more expeditious processing of projects that contain a number of distinct elements, some of which are in conformance with MHCC plans and policy and should be allowed to go forward quickly and other elements that do not conform, but, if modified or eliminated, make approval of the entire project feasible. Given the multi-faceted nature of many projects and the fact that such projects can be modified in ways that improve compatibility with the State Health Plan and CON law, without compromising feasibility, this option that aims to make the project review process more collaborative.